

Original Article

Therapeutic effect and safety of laparoscopic cervical cerclage for treatment of cervical insufficiency in first trimester or non-pregnant phase

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Abstract: Objective: To investigate the therapeutic effect and safety of cerclage placed in pregnancy via laparoscopy (CPL) in the first trimester or in non-pregnant phase (CNL). Methods: A total of 134 cervical insufficiency patients who were treated with cervical cerclage were included. All the patients were divided into 3 groups. CPL group: 43 cases were treated with cerclage placed in pregnancy via laparoscopy in the first trimester, of which 26 cases received termination of pregnancy. CNL group: 58 cases were treated with cerclage placed via laparoscopy in the non-pregnant phase, of whom 34 received termination of pregnancy. TVC group: 33 cases received traditional vaginal cerclage placed in second trimester, of whom 33 cases received termination of pregnancy. Results: All patients received a successful operation without any complications during or after surgery. The post-operative hospitalization duration in CPL group was significantly shorter than that in TVC group. In 3 groups, for all patients who received termination of pregnancy, the postoperative full term delivery rate, fetal salvage rate (if pregnancy lasted ≥ 14 weeks), mean gestational weeks (if pregnancy lasted ≥ 14 wk) after operation, post-operation gestational age for all patients, and weeks of pregnancy gained were observed and analyzed. There were no significant differences of every index between CPL group and CNL group. Every index in TVC group was lower than that in both CNL group and CPL group. Conclusion: CPL or CNL for treatment of cervical insufficiency is safe and effective, with a better therapeutic effect than that of TVC in the second trimester.

Keywords: Cerclage placed via laparoscopy, cervical insufficiency, pregnancy outcome

Introduction

In pregnant women, the incidence of cervical insufficiency is 1%, with a high recurrence rate of 30%, and it will mainly result in abortion or premature delivery in the second and third trimester [1, 2]. Traditional vaginal cerclage in the second trimester was the main treatment of cervical insufficiency [3], which would partly solve the problem [4, 5]. However, it failed to achieve an ideal effect in some patients, especially in patients with uterus deformity, uterus laceration and a failed TVC treatment. In recent years, there have been some reports about treating cervical insufficiency with cerclage placed via laparoscopy in non-pregnant phase [6-8]. We searched the literature about laparoscopic cervical cerclage in PubMed, EMBASE, and Cochrane database, and concluded that most cases received a better prognosis to

some extent (**Table 1**) [9, 10]. There were still some problems remained unsolved: what are the advantages of cerclage placed via laparoscopy compared to TVC; should cerclage placed via laparoscopy be operated before or after pregnancy; will fertilization be affected if cerclage placed via laparoscopy is operated before pregnancy; and what is the appropriate time of fertilization if cerclage placed via laparoscopy is operated before pregnancy? Compared with traditional vaginal cerclage in the second trimester, this study was aimed to investigate the therapeutic effect and safety of CPL and CNL, in order to solve the problems above.

Materials and methods

General data

A total of 134 cervical insufficiency patients who had fertility will and required cervical cer-

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Table 1. Cumulative results of laparoscopic cervical cerclage

Cerclage by laparoscopy: study and year	Patient no.	The time of surgery	Pregnancy no.	Intraoperative complication rate (%)	Fetal survival rate (%)	Mean GA at birth
Lesser KB et al., 1998	1	During pregnancy	1	0	100	Not reported
Mingione MJ et al., 2003	11	Before pregnancy	12	9	83	37.1
Cho CH et al., 2003	20	During pregnancy	21	0	95	36.2
Gallot D et al., 2003	3	Before pregnancy	2	0	100	38
Ghomi A et al., 2006	1	Before pregnancy	1	0	100	38.4
Aboujaoude R et al., 2007	1	During pregnancy	Not reported	0	Not reported	Not reported
Agdi M et al., 2008	1	Before pregnancy	1	0	Not reported	Not reported
Reid GD et al., 2008	3	During pregnancy	3	0	Not reported	Not reported
Liddell HS and Lo C., 2008	11	Before pregnancy	10	0	100	Not reported
Whittle WL et al., 2009	65	34 not pregnant, 31 pregnant	67	10.7	80	35.8
Fechner AJ et al., 2009	1	During pregnancy	1	0	100	37
Carter JF et al., 2009	12	7 not pregnant, 5 pregnant	12	0	75	Not reported
Pereira RM et al., 2009	1	Before pregnancy	2	0	100	38
Pawlowicz P et al., 2009	2	Before pregnancy	Not reported	0	Not reported	Not reported
Murray A et al., 2011	1	Before pregnancy	1	Not reported	100	28
DaCosta V et al., 2011	3	Before pregnancy	2	0	100	37
Riiskjaer M et al., 2012	52	Before pregnancy	45	0	83.3	37.4
El-Nashar SA et al., 2013	4	During pregnancy	4	Not reported	100	37.3
Salmeen KE and Parer JT., 2013	66	Before pregnancy	36	4.5	90	37.2
Ades A et al., 2014	64	61 not pregnant, 3 pregnant	35	1.6	95.8	35.8
Shin JE et al., 2014	1	During pregnancy	1	0	100	35
Luo L et al., 2014	19	Before pregnancy	15	0	90	36.4
Current study	101	58 not pregnant, 43 pregnant	93	0	95	36.2

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Table 2. Demographic variable linked with the three groups [$\bar{x} \pm SD$ or Cases (%)]

Group	For all patients			For patients of termination pregnancy		
	CPL (n = 43)	CNL (n = 58)	TVC (n = 33)	CPL (n = 26)	CNL (n = 34)	TVC (n = 33)
Mean maternal age at cerclage	29.07 \pm 3.76	29.28 \pm 3.28	29.94 \pm 4.04	29.85 \pm 4.29	29.00 \pm 3.26	29.94 \pm 4.04
Mean gravidity	2.42 \pm 1.01	2.14 \pm 0.91	1.97 \pm 0.85	2.42 \pm 0.95	2.12 \pm 1.01	1.97 \pm 0.85
Patient with previous term pregnancy	n = 2 (4.65%)	n = 1 (1.72%)	n = 0	n = 0	n = 0	n = 0
No. of previous living children	n = 2 (4.65%)	n = 2 (3.35%)	n = 0	n = 0	n = 0	n = 0
Mean GA prior to cerclage	22.25 \pm 3.67	21.36 \pm 3.64	22.08 \pm 3.04	21.91 \pm 1.77	20.80 \pm 4.06	22.08 \pm 3.04
No. of prior T1 SA	n = 1	n = 0	n = 1	n = 0	n = 0	n = 0
No. of prior T1 SA	n = 43	n = 58	n = 33	n = 26	n = 34	n = 33

Footnote: There were no statistically differences between each two groups. CPL, cerclage placed in pregnancy via laparoscopy; CNL, cerclage placed nonpregnant via laparoscopy; TVC, traditional vaginal cerclage; GA, gestational age.

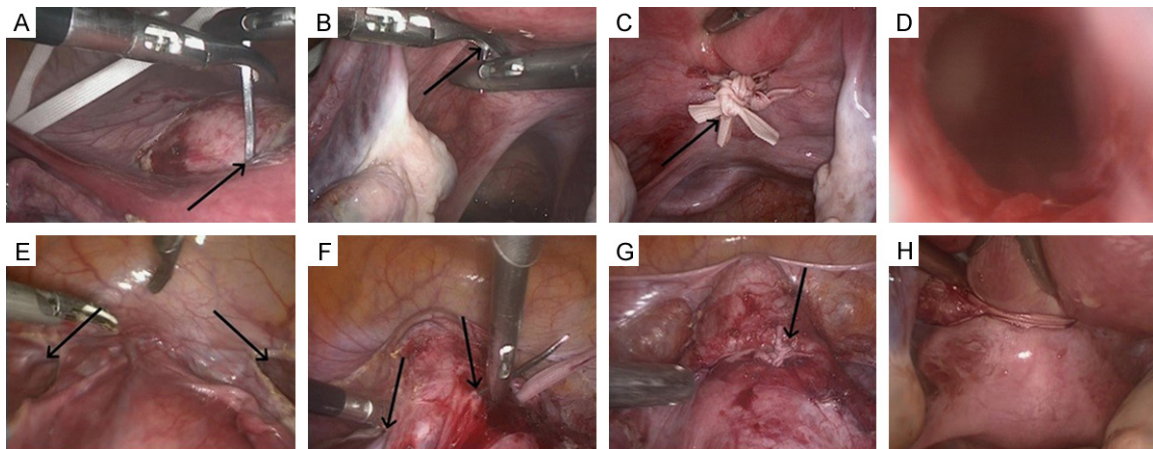


Figure 1. A: Straight entry point of needle in the non-pregnant state; B: Straight exit point of needle in the non-pregnant state; C: Cerclage location in the non-pregnant state; D: Hysteroscopy; E: Surgical approach in the pregnant state with opened broad ligament; F: Straight entry and exit points of needle in the pregnant state; G: Cerclage location in the pregnant state; H: Dorsal surface of the uterus in the pregnant state.

clage treatment were included. Briefly, 96 cases of them never received any cervical cerclage treatment, and 38 cases of them received TVC treatment before. None of the patients received cerclage placed via laparoscopy before. All patients have signed the informed consent, and this study was approved by institutional research ethics committee. General conditions of all patients in three groups are shown in **Table 2**.

Inclusion criteria and indication of operation

Medical history of spontaneous abortion or pre-term delivery in second or third trimester, diagnosed cervical insufficiency, and fertility will.

Exclusion criteria of cerclage placed via laparoscopy

1). A complication of intrauterine adhesion or uterus myoma in septum and submucosa

2). Medical history of pelvic surgery, a possibility of pelvic comprehensive adhesion

3). Patients with cervical cerclage in first trimester, before this operation, had a medical history of threatened abortion, or a medical history of diagnosed inevitable abortion, or a medical history of missed abortion.

Exclusion criteria of TVC treatment in second and third trimester

1). Vaginitis, acute or sub-acute amniotitis, pelvic inflammation

2). Premature rupture of fetal membranes.

Appropriate operation type was chosen according to patients' conditions and wills after they were fully informed: If patients were in the second or third trimester, TVC was recommended; if patients were in the first trimester, CPL in the

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first trimester and TVC in the second or third trimester were recommended; if patients were not pregnant, CNL in non-pregnant phase, CPL in the first trimester, and TVL in the second or third trimester, were all appropriate.

Of all the 134 patients included, 43 cases were treated with CPL in the first trimester (< 14 gestational weeks) (CPL group), 58 cases were treated with CNL in non-pregnant phase (CNL group), 33 cases were treated with TVC in the second or third trimester (TVC group). Cohort study was conducted.

Cervical cerclage via laparoscopy

Tracheal general anesthesia was applied.

CNL: Operating levers was put into uterine cavity to support uterus, and peritoneum covering bladder and uterus was incised using ultrasonic scalpel. Uterus isthmus and blood vessels were exposed after bladder was push down. On the two sides of uterus isthmus, cervical muscular tissue in the medial side of uterus blood vessels (close to the cervical inner orifice) was chosen as the needle insertion point (**Figure 1A**). A Mersilene encircling band, 5 mm in width, with needles on both ends, was used. Straight needle was inserted from anterior at the point chosen above, and left from the posterior of ipsilateral uterus isthmus (**Figure 1B**). The knot was tied on the dorsal surface of uterus to prevent possible irritation sign of bladder (**Figure 1C**). The encircling band was strained till the cervical inner orifice could only contain 6-gauge cervical dilator. The second encircling band was placed right a little upper to the first one the same way as above. Laparoscopic tubal perfusion was performed to confirm that the ovarian ducts remained unobstructed. At last, hysteroscopy examination was performed to make sure that encircling band was in muscular layer, without piercing out of cervix or cervical mucosa (**Figure 1D**).

CPL: Because it is impossible to support the uterus with operating levers during pregnancy, ultrasonic scalpel was used to cut up bilateral round ligaments and broad ligaments peritoneum. Cervical isthmus and uterus vessels were exposed after uterovesical peritoneal reflection was cut up (**Figure 1E**). On the two sides of uterus isthmus, the medial side of uterus blood vessels was chosen as the withdraw-

ing needle points. Straight needle carrying one end of Mersilene suture was inserted from posterior of cervix (**Figure 1F**) and left from the point chosen above. The other end of the suture was hauled to the other side of cervix from the posterior of uterus, and the same process was performed as before. The Mersilene band was strained as tight as possible, and the knot was tied in the anterior of cervix (**Figure 1G, 1H**). The second Mersilene band was placed right a little upper to the first one the same way as above. Hysteroscopy examination was not needed.

Treatment after operation: At the end of the operation, laparoscopy was removed and the air in enterocoelia was evacuated. Abdominal wall and skin were repaired. Antibiotics was given only once during perioperative period. After 2 days of observation, patients were allowed to leave hospital if there were no signs of fever, abdominal pain or vaginal bleeding. Cesarean delivery was recommended. Encircling band was not needed to be removed.

TVC

Cervical local anesthesia was applied. Bivalve speculum was used to expose cervix. After vagina and cervix were disinfected, regional anesthesia was performed to cervix. Carrying 10-gauge suture, great curve needle was inserted from the 11-10 o'clock of cervix, where bladder was attached to. The suture went through muscularis mucosae to draw the cervix a little higher, and continued to make purse string at 8-7 o'clock, 5-4 o'clock, and 2-1 o'clock of cervix. A double button ligation was tied on the cervical front lip till the cervix can only contain a fingertip. Patients received fully rest after operation till the delivery. Suture could be removed when the labor was onset. Vaginal delivery was also recommended. All operations were accomplished by a same chief physician with high qualification.

Statistical analysis

SPSS 13.0 software was used in the analysis. Measurement data were documented with means \pm standard deviation (SD), and quantitative data were documented with cases (%). With comparison of quantitative data between multiple groups, one-way analysis of variance was conducted if the data showed a normal dis-

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Table 3. Main outcome of patients among three groups (Cases)

Variable	CPL (n = 43)	CNL (n = 58)	TVC (n = 33)
Not pregnant	-	n = 8	-
Still being pregnant	n = 17	n = 16	n = 0
Abortion	n = 1	n = 2	n = 10
Delivery	n = 25	n = 32	n = 23

tribution with an equal variance, and Post Hoc was conducted if a multiple comparison was needed. If the conditions above were not met, Kruskal-Wallis H test would be used to conduct multiple comparisons between groups. In that case, Rank cases were used for coding rank, and then rank orders were used to conduct multiple comparisons of variance analysis. As for quantitative data, chi-square test or continuous corrected chi-square test was conducted for the analysis. If the conditions for chi-square test or continuous corrected chi-square test were not met, Fisher exact probability would take the role. If double variants accorded with normal distribution, the correlation analysis would be conducted using Person analysis, and will be replaced by Spearman analysis if the normal distribution was not shown. $P < 0.05$ was considered significantly different.

Results

General conditions after operation

All operations were successful without assistance of open operations. There were no complications such as bleeding, infection, and injury of peripheral organs. Patients treated with laparoscopic operation were allowed to leave hospital one week after this surgery. Hospitalization time after operation showed a significant difference between 3 groups ($F = 80.488$, $df = 2$, $P = 0.000$) and was recorded respectively as following: CPL group 3.15 ± 1.41 d, CNL group 1.53 ± 0.66 d, TVC group 5.73 ± 4.15 d.

Outcomes of post-operation pregnancy

In CPL group, 26 cases received termination of pregnancy, and 1 case presented a spontaneous abortion with an unclear reason. In CNL group, 8 patients didn't show any signs of pregnancy. 50 patients were pregnant, of which 34 cases received termination of pregnancy.

One case presented a spontaneous abortion due to chromosome abnormalities at 4 weeks of pregnancy, and treated with complete curettage of uterine cavity. One case received drug-induced abortion because of stagnation of embryonic development at 14 weeks of pregnancy. In TVC group, 24 cases had a successful vaginal birth while 9 cases presented a spontaneous abortion in the third trimester. The outcomes of post-operation pregnancy in three groups were showed in **Table 3**. In CPL and CNL group, all patients were treated with caesarean section, without encircling band removed. For the neonates in three groups, there were no needs of intensive care, no neonatal death, and no sequelae of prematurity.

For patients who were pregnant and received termination of pregnancy successfully in three groups, the comparisons of the outcomes are shown in **Table 4**. Among three groups, significant difference was shown in full term delivery rate ($\chi^2 = 18.678$, $df = 2$, $P = 0.000$), in mean gestational weeks (if pregnancy lasted ≥ 14 wk) after operation ($F = 17.771$, $df = 2$, $P = 0.000$), in post-operation gestational age for all patients ($F = 14.898$, $df = 2$, $P = 0.000$), in weeks of pregnancy gained ($F = 12.678$, $df = 2$, $P = 0.000$).

Multiple comparison between every two groups

CPL group and CNL group: there were not significant differences in every index of post-operation pregnancy ($P > 0.05$).

CPL group and TVC group: significant differences were shown in indexes such as full term delivery rate (24/26 VS 15/33, $P = 0.000$), fetal survival rate (25/25 VS 23/32, $P = 0.000$), mean gestational weeks (if pregnancy lasted ≥ 14 wk) (37.88 ± 0.83 VS 32.91 ± 7.20 , $P = 0.000$), post-operation gestational age for all patients (35.71 ± 7.15 VS 31.30 ± 7.88 , $P = 0.000$), and weeks of pregnancy gained (16.00 ± 1.96 VS 10.69 ± 5.93 , $P = 0.000$).

CNL group and TVC group: significant differences were shown in indexes such as full term delivery rate (28/34 VS 15/33, $P = 0.000$), neonatal survival rate (32/33 VS 23/32, $P = 0.000$), mean gestational weeks (if pregnancy lasted ≥ 14 wk) (36.67 ± 4.51 VS 32.91 ± 7.20 , $P = 0.000$), post-operation gestational age for all

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Table 4. Comparison of pregnant outcomes among three groups [$\bar{x} \pm SD$ or Cases (%)]

Data	CPL group (n = 26)	CNL group (n = 34)	TVC group (n = 33)	χ^2 or F (df)	P	P value (CPL vs CNL)	P value (CPL vs TVC)	P value (CNL vs TVC)
T1 SA	n = 1	n = 1	n = 1					
T2 SA	n = 0	n = 1	n = 9					
Premature delivery	n = 1	n = 4	n = 8					
Term delivery	n = 24	n = 28	n = 15	18.678 (2)	0.000	0.459	0.000	0.002
Fetal salvage rate	25/25	32/33	23/32			0.569	0.012	0.014
GA if pregnancy lasted ≥ 14 wk*	37.88 \pm 0.83	36.67 \pm 4.51	32.91 \pm 7.20	17.771 (2)	0.000	0.434	0.000	0.000
GA for all patients*	36.73 \pm 5.92	35.71 \pm 7.15	31.30 \pm 7.88	14.898 (2)	0.000	0.521	0.000	0.000
Birth weight (g)*	3006.00 \pm 402.94	2885.94 \pm 437.41	2762.50 \pm 591.10	0.197 (2)	0.821	0.713	0.553	0.767
Weeks of pregnancy gained	16.00 \pm 1.96	14.58 \pm 5.63	10.69 \pm 5.93	12.678 (2)	0.000	0.065	0.000	0.001

Footnote: T1 SA, first trimester spontaneous abortion; T2 SA, second trimester spontaneous abortion; *Values are average (range). Fetal salvage rate (if pregnancy lasted ≥ 14 wk) was defined as the ratio of live fetus number and the total number of pregnancy (excluding the number of continuous pregnancy and the number of abortions within 14 wk). Weeks of pregnancy gained were the differences between the weeks of first abortion or delivery after surgery and the average weeks of all spontaneous abortions or deliveries before surgery (excluding abortions within 14 wk).

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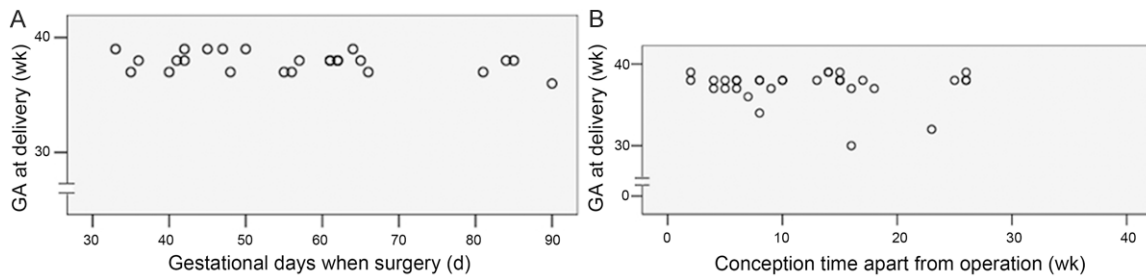


Figure 2. A: Relationship between gestational days when surgery and GA at delivery; B: Relationship between conception time apart from operation and GA at delivery.

patients (36.73 ± 5.92 VS 31.30 ± 7.88 , $P = 0.000$), and weeks of pregnancy gained (16.00 ± 1.96 VS. 10.69 ± 5.93 , $P = 0.000$).

Analysis of correlation between pregnancy and operation

In CPL group, for the 25 patients who received termination of pregnancy, the correlation between gestational time before CPL and gestational weeks at delivery was demonstrated (**Figure 2A**). The correlation coefficient was $r_s = -0.121$, $P = 0.555$, showing no significant correlation.

In CNL group, for the 32 patients who received termination of pregnancy, the correlation between interval time before fertilization and gestational weeks at delivery was demonstrated (**Figure 2B**). The correlation coefficient was $r_s = 0.130$, $P = 0.464$, showing no significant correlation.

Discussion

Cervical insufficiency was caused by defects in cervical structure or function. If pregnancy cannot be maintained to full term, in the second or the third trimester, there will be premature rupture of fetal membranes or pregnant capsule intruding into vagina or even pregnant capsule discharged out of the uterine. Cervical insufficiency has become one of the leading causes of recurrent abortion and premature labor in the second or the third trimester [2, 4]. TVC, as a traditional method, was usually placed in the second and the third trimester or used as an emergency treatment for threatened abortion and premature labor in the second and the third trimester [4, 11]. Because the operation was performed in vagina and in pregnancy, bladder was not push down, in order to prevent

the stretching of cervix. The position of knot was located below cervical inner introitus, close to the cervical outer orifice and 10-gauge suture was used. However, what really supports the pregnant uterine was only the encircling string and the cervical tissue beneath it, which resulted in an insufficient power and a high rate of failure.

It is still a problem how the full term labor rate could be improved. We placed laparoscopic cervical cerclage in non-pregnant phase and the first trimester (< 14 gestational weeks), showing that CPL and CNL could shorten the hospitalization time and prolong the gestational weeks compared with TVC. In CPL group and CNL group, the indexes such as the full term delivery rate, fetal salvage rate (if pregnancy lasted ≥ 14 weeks), mean gestational weeks (if pregnancy lasted ≥ 14 wk) after operation, post-operation gestational age for all patients, and weeks of pregnancy gained, were all significantly higher than those in TVC group ($P < 0.05$) (**Table 3**). It has been proved that CPL and CNL have advantages compared with TVC [1, 6, 12-17], probably the reason could be shown as following: 1). With laparoscope, cervix could be fully exposed after bladder was pushed down. Therefore the encircling band could be sutured above the cervical inner orifice accurately (**Figure 1G**). 2). Two relative wide encircling bands could be used in the operation so that the problem of cervical anatomic defects was fundamentally solved, with the mechanical requirement of a pregnant uterine well satisfied [9]. 3). Stable encircling band and the enough cervical tissue beneath it could well support the pregnant uterine during the whole pregnancy, enhance the bearing capacity of cervix and prevent the cervical orifice from dilating with gestational weeks increasing. Therefore, abor-

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tion or premature delivery could be avoided effectively with gestational weeks prolonged and outcomes of pregnancy obviously improved.

Should the CPL and CNL be placed during non-pregnant phase or the first trimester? We concluded from this study that, every index (including full term delivery rate, fetal salvage rate (if pregnancy lasted ≥ 14 weeks), mean gestational weeks (if pregnancy lasted ≥ 14 wk) after operation, post-operation gestational age for all patients, and weeks of pregnancy gained) of CPL and CNL was similar, without a significant difference (**Table 3**), indicating CPL is as safe as CNL.

Frankly, there was risk of abortion if laparoscopic cervical cerclage was placed in pregnancy. In order to improve the safety and success rate, patients with gestational weeks less than 14 weeks were chosen. Uterus was less sensitive with less gestational weeks, therefore risk of uterus contraction decreased. Using laparoscope, there was no need of drawing the cervix when push down the bladder and suture the cervical inner orifice, so the pregnant uterus received less irritation. There was no incisions in vagina, which reduced the risk of abortion and infection. In addition, there was some technical improvement in CPL compared with CNL: 1). In order to reduce the irritation uterine got, operational levers were not used. 2). The straight needle carrying the encircling band was inserted from posterior to anterior (**Figure 1F**), and the knot was tied in the anterior of uterus. Uterus was swayed as less as possible to reduce the irritation. At the same time, the knot was fully exposed making it easier to tie the knot and examine whether the knot was strained tight without swaying the uterus. 3). Hysteroscopy examination was not needed after operation.

Compared with CNL, CPL may increase the hospitalization time, but patients could still leave hospital within one week after operation, which were both shorter than that of TVC. For patients received CPL, the normal life and work would not be affected, and long term of bedding to recover is not necessary. Progesterone injection through muscle would be enough for tocolytic effect. Antibiotic treatment was given before and after operation respectively for peri-operative prevention of infection. The correlation analysis between CPL placed time and ges-

tational weeks at delivery (**Figure 1**) showed that there was not an obvious correlation. So for cervical insufficiency patients, CPL placement was recommended at any time within 14 weeks of pregnancy. While in the third trimester, laparoscopic vision field was blocked by a bigger uterus, CPL was not recommended. Whether CPL could be placed in the second trimester is worthy of further investigation.

What we are really concerned about is whether CNL will affect the fertilization after operation. In the CNL operation, after the encircling band was placed, not only tubal perfusion was performed to make sure the oviduct was unblocked, but also the hysteroscopy examination was performed to make sure the encircling band was not piercing out of uterine endometrium. Theoretically, in cervical cerclage placement, encircling band was embed in the cervical muscular tissue of isthmus (close to the cervical inner orifice) without piercing out of cervix or endometrium to become foreign bodies, and it would not affect the sperm passing through the cervix or the capacity of uterus. The encircling band was used to tight the cervix instead of ovaries or its vessels, so the ovaries' function was not affected. A minimally invasive laparoscope was used with a low possibility of pelvic adhesion. Therefore, CNL is considered to have no influence on fertilization. There was no significant correlation between fertilization time in CNL patients and gestational weeks at delivery. Any time of fertilization after operation would be appropriate, and there is no need of waiting.

In summary, compared with TVC in the second or third trimester, laparoscopic cervical cerclage is a safe and effective treatment. For cervical insufficiency patients, it can effectively prolong the gestational weeks, and improve the full term labor rate and fetal lavage rate, with a shorted time to recover. The operation would be safe and effective both in non-pregnant phase and the first trimester. A longer and larger-scale follow-up visit remains worthy and necessary.

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Disclosure of conflict of interest

None.

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